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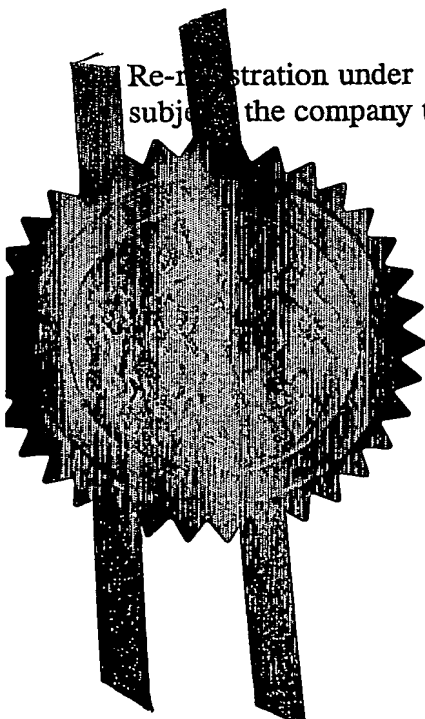
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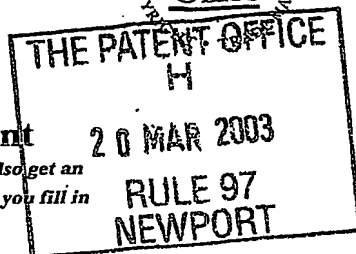
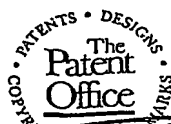
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21MAR03 E794016-1 D02884
P01/7700 0.00-0306472.2

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The Patent Office

Cardiff Road
Newport
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NP10 8QQ

1. Your reference P32893-/CMU/RTH/RMC

2. Patent application number
(The Patent Office will fill in this part)

20 MAR 2003

0306472.2

3. Full name, address and postcode of the or of each applicant (underline all surnames)

AorTech International plc
Phoenix Crescent
Strathclyde Business Park
Bellshill
Lanarkshire, ML4 3NJ

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

77 2824 9001

4. Title of the invention

"Valve"

5. Name of your agent (if you have one)

Murgitroyd & Company

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Scotland House
165-169 Scotland Street
Glasgow
G5 8PL

Patents ADP number (if you know it)

1198015

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

Yes

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
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Description

38

Claim(s)

Abstract

Drawing(s)

15

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Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature *Murgitroyd & Company* Date 19 March 2003
Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom

ROISIN MCNALLY

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1 **"Valve"**

2
3 The present invention relates to artificial heart
4 valves, more particularly to flexible leaflet heart
5 valves which are used to replace natural aortic or
6 pulmonary valves of the heart.

7
8 Ideally artificial heart valves should work in a
9 similar fashion to natural heart valves in that when
10 blood flows in a particular direction the valve
11 adopts an open position to permit blood flow through
12 it, whereas when blood tries to flow in the opposite
13 direction the valve adopts a closed position
14 preventing the flow of blood in the reverse
15 direction through the valve (regurgitation).

16
17 Natural heart valves use thin flexible tissue
18 leaflets as the closing members. In the closed
19 position the leaflets are arranged such that each
20 leaflet contacts its neighbour. This arrangement
21 serves to close the valve and prevent the back flow
22 of blood through the valve. In the open position

1 the leaflets separate from each other and move
2 radially towards the inner walls of the blood vessel
3 in which the valve is located. This open
4 configuration of the valve permits the flow of blood
5 through the valve.

6
7 A number of artificial cardiac valves have been
8 produced which comprise leaflets which open and
9 close in a similar fashion to natural valve
10 leaflets. However, although the artificial valves
11 work in a similar manner to the natural valves, the
12 geometries of the leaflets differ due to the
13 properties of the materials used in the construction
14 of the synthetic heart valves.

15
16 A number of factors have to be considered when
17 designing artificial heart valves of similar design
18 to natural heart valves. These include the pressure
19 gradient required to open and close the leaflets of
20 the valve, regurgitation, blood handling and
21 durability of the valve.

22
23 The leaflets of both natural and synthetic heart
24 valves must be capable of withstanding a high back
25 pressure across the valve when they are in the
26 closed position, yet be capable of opening with a
27 minimum of pressure across the valve in the forward
28 direction of blood flow.

29
30 This is necessary to ensure correct operation of the
31 valve even when blood flow is low. Further the
32 valve should open quickly and as wide as possible

1 when blood flows in the desired direction. The
2 maximum orifice of the valve in the open position is
3 generally dictated by the width of the valve.

4

5 In order to minimise closing regurgitation (reverse
6 blood flow through the closing valve) in the closed
7 position of the valve, the free edges of the
8 leaflets should come together to form a seal to
9 minimise the reverse flow of blood.

10

11 The valve design and the materials used for valve
12 construction should minimise the activation of both
13 the coagulation system and platelets. The flow of
14 blood through the valve should avoid exposing blood
15 to either regions of high shear or relative stasis.

16

17 In addition, in order to be suitable for
18 implantation, synthetic valves should be
19 sufficiently durable such that they are clinically
20 functional for at least 20 years. Durability of the
21 synthetic leaflets depends on the materials from
22 which the leaflets are constructed and also the
23 stresses to which the leaflets are subjected during
24 use. Although several materials have suitable
25 hydrodynamic properties, many valves constructed
26 using materials with suitable hydrodynamic
27 properties fail during use, due to fatigue caused by
28 the repeated stresses of cycling from a closed to an
29 open position.

30

31 Conventional heart valves typically comprise an
32 annular frame disposed perpendicular to the blood

1 flow. The annular frame generally has three posts
2 extending in the downstream direction defining three
3 generally U-Shaped openings or scallops between the
4 posts. The leaflets are attached to the frame
5 between the posts along the edges of the scallops
6 and are unattached at the free edges of the leaflets
7 adjacent to the downstream ends of the posts.
8 A valve design, comprising a leaflet geometry which
9 was elliptical in the radial direction and
10 hyperbolic in the circumferential direction in the
11 closed valve position, with leaflets dip-coated from
12 non-biostable polyurethane solutions onto injection-
13 moulded polyurethane frames has attained
14 durabilities in excess of 800 million cycles during
15 *in vitro* fatigue testing (Mackay TG, Wheatley DJ,
16 Bernacca GM, Hindle CS, Fisher AC. New polyurethane
17 heart valve prosthesis: design, manufacture and
18 evaluation. *Biomaterials* 1996; 17:1857-1863; Mackay
19 TG, Bernacca GM, Wheatley DJ, Fisher AC, Hindle CS.
20 *In vitro* function and durability assessment of a
21 polyurethane heart valve prosthesis. *Artificial*
22 *Organs* 1996; 20:1017-1025; Bernacca GM, Mackay TG,
23 Wheatley DJ. *In vitro* function and durability of a
24 polyurethane heart valve: material considerations. *J*
25 *Heart Valve Dis* 1996; 5:538-542; Bernacca GM, Mackay
26 TG, Wilkinson R, Wheatley DJ. Polyurethane heart
27 valves: fatigue failure, calcification and
28 polyurethane structure. *J Biomed Mater Res* 1997;
29 34:371-379; Bernacca GM, Mackay TG, Gulbransen MJ,
30 Donn AW, Wheatley DJ. Polyurethane heart valve
31 durability: effects of leaflet thickness. *Int J*
32 *Artif Organs* 1997; 20:327-331.)). However, this

1 valve design became unacceptably stenotic in small
2 sizes. Thus, a redesign was effected, changing the
3 hyperbolic angle from the free edge to the leaflet
4 base, and replacing the injection-moulded frame with
5 a rigid, high modulus polymer frame. This redesign
6 permitted the use of a thinner frame, thus
7 increasing valve orifice area. This valve design,
8 with a non-biostable polyurethane leaflet material,
9 was implanted in a growing sheep model. Over the six
10 month implant period the region close to the frame
11 posts on the inflow side of the valve, at which full
12 leaflet opening was not achieved, suffered a local
13 accumulation of thrombus (Bernacca GM, Raco L,
14 Mackay TG, Wheatley DJ. Durability and function of a
15 polyurethane heart valve after six months *in vivo*.
16 Presented at the XII World Congress of International
17 Society for Artificial Organs and XXVI Congress of
18 the European Society for Artificial Organs,
19 Edinburgh, August 1999. Wheatley DJ, Raco L,
20 Bernacca GM, Sim I, Belcher PR, Boyd JS.
21 Polyurethane: material for the next generation of
22 heart valve prostheses? Eur. J. Cardio-Thorac. Surg.
23 2000; 17; 440-448). This valve design used non-
24 biostable polyurethane, which had tolerable
25 mechanical durability, but which showed signs of
26 polymer degradation after six months *in vivo*.

27

28 International Patent Application WO 98/32400
29 entitled "Heart Valve Prosthesis" discloses a
30 further design, using closed leaflet geometry,
31 comprising essentially a trileaflet valve with
32 leaflets moulded in a geometry derived from a sphere

1 towards the free edge and a cone towards the base of
2 the leaflets. The spherical surface, defined by its
3 radius, is intended to provide a tight seal when the
4 leaflets are under back pressure, with ready opening
5 provided by the conical segment, defined by its
6 half-angle, at the base of the leaflets. It is
7 stated that where the spherical portion is located
8 at the leaflet base, an advantage is provided in
9 terms of the stress distribution when the valve is
10 closed and under back pressure.

11
12 U.S. Patent No. 5,376,113 entitled "Closing Member
13 Having Flexible Closing Elements, Especially a Heart
14 Valve" issued December 27, 1994 to Jansen et al.
15 discloses a method of producing flexible heart valve
16 leaflets using leaflets attached to a base ring with
17 posts extending from this upon which the leaflets
18 are mounted. The leaflets are formed with the base
19 ring in an expanded position, being effectively of
20 planar sheets of polymer, which become flaccid on
21 contraction of the ring. The resulting valve is
22 able to maintain both a stable open and a stable
23 closed position in the absence of any pulsatile
24 pressure, though in the neutral unloaded position
25 the valve leaflets contain bending stresses. As a
26 consequence of manufacturing the valve from
27 substantially planar sheets, the included angle
28 between the leaflets at the free edge where they
29 attach to the frame is 60° for a three leaflet valve.

30
31 U.S. Patent No. 5,500,016 entitled "Artificial Heart
32 Valve" discloses a valve having a leaflet shape

1 defined by the mathematical equation $z^2 + y^2 = 2RL$
2 $(x-g)-\alpha(x-g)^2$, where g is the offset of the leaflet
3 from the frame, RL is the radius of curvature of the
4 leaflet at $(g,0,0)$ and α is the shape parameter and
5 is >0 and <1 .

6
7 A valve design having a partially open configuration
8 when the valve is not subject to a pressure
9 gradient, but assuming a fully-open position during
10 forward flow is disclosed in International Patent
11 Application WO. 97/41808 entitled "Method for
12 Producing Heart Valves". The valve may be a
13 polyurethane trileaflet valve and is contained
14 within a cylindrical outer sleeve.

15
16 International Patent Application WO 01/41679
17 discloses a heart valve wherein the leaflets have
18 been designed to facilitate wash out of the whole
19 leaflet orifice including the area close to the
20 frame posts. This Application teaches that stresses
21 are highest in the region of the commissures where
22 loads are transmitted to the stent, but they are
23 reduced when the belly of the leaflet is as low as
24 practicable in the closed valve. To ensure a belly
25 in the leaflet, the above application indicates that
26 there must be sufficient material in the leaflet.
27 Further this application indicates that under back
28 pressure, in the closed position, the shape of the
29 leaflet can be defined by elliptical or hyperbolic
30 coordinates.

31

1 A number of designs have been suggested for use in
2 cardiac heart valves to ensure that the heart valves
3 have sufficient leaflet material such that the valve
4 is capable of opening as wide as the maximum
5 possible orifice of the valve, that such opening
6 requires as little energy as possible and further
7 that regurgitation of blood through the valve is
8 minimised.

9
10 However, the designs which have been previously
11 described generally have not considered the stresses
12 applied to the leaflets during the cycling of
13 opening and closing of the valve.

14
15 It would be advantageous to provide a synthetic
16 valve leaflet geometry that minimises the stresses
17 present in the leaflets of the valve during cycling
18 from the closed to the open position and back to the
19 closed position increase the lifetime of the
20 synthetic leaflets.

21
22 According to the present invention there is provided
23 a cardiac valve prosthesis comprising:

24
25 a frame and at least two flexible leaflets;
26
27 wherein the frame comprises an annular portion
28 which, in use, is disposed substantially
29 perpendicular to the blood flow, the frame
30 having first and second ends, one of the ends
31 defining at least two scalloped edge portions
32 separated and defined by at least two posts,

1 each leaflet being attached to the frame along
2 a scalloped edge portion and being movable
3 between an open and a closed position,
4

5 each of the at least two leaflets having a
6 blood inlet side, a blood outlet side and at
7 least one free edge, the at least two leaflets
8 being in a closed position when fluid pressure
9 is applied to the outlet side such that the at
10 least one free edge of a first leaflet is urged
11 towards the at least one free edge of a second
12 or further leaflet, and the at least two
13 leaflets being in an open position when fluid
14 pressure is applied to the blood inlet side of
15 the at least two leaflets such that the at
16 least one free edge of the first leaflet is
17 urged away from the at least one free edge of
18 the second or further leaflet;
19

20 wherein in a first plane perpendicular to the
21 blood flow axis the length of each leaflet in a
22 circumferential direction (XY) between the
23 posts at any position along the longitudinal
24 axis (Z) of a post is defined by a parabolic
25 function.
26

27 Preferably the length of a leaflet in the
28 circumferential direction (XY) between the posts at
29 any position along the longitudinal axis (Z) of a
30 post (Z) is defined by the function:
31
32

1 Function of a parabola

$$2 \quad Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

3

4 Wherein $Y_z = Y$ offset at a particular co-ordinate X
5 and Z

6 $R =$ parabolic maximum

7 $L_z =$ straight line distance between a
8 first post and a second post of the frame
9 at a height Z

10 $x =$ distance from origin of post towards
11 another post

12

$$13 \quad \text{Length} = \int_0^L \sqrt{1 + \left(\frac{dy}{dx} \right)^2} dx$$

14

15 It is understood that a parabolic function includes
16 any pseudotrigonmetric, pseudoelliptical, smooth
17 function or table of values that describe a geometry
18 which is substantially parabolic.

19

20 The use of a pseudo function to describe a parabolic
21 function will be obvious to one skilled in the art.

22

23 Preferably the cast shape of the leaflet in the
24 circumferential direction (XY) at any position along
25 the longitudinal axis (Z) of a post is defined by a
26 first wave having a first frequency.

27

28 Preferably the first wave is a sinusoidal wave.

29

1 More preferably the cast shape of the leaflet in the
2 circumferential direction (XY) at any position along
3 the longitudinal axis (Z) of a post is defined by at
4 least two waves of differing frequency, which form a
5 composite wave.

6
7 Preferably the length of the leaflet in the
8 circumferential direction (XY) between the posts at
9 any position along the longitudinal axis (Z) of a
10 post is defined by a parabolic function and at least
11 one correction factor.

12
13 Preferably a correction factor is used to compensate
14 for inward movement of the prosthesis posts on
15 closure of the valve.

16
17 Preferably a correction factor is used to compensate
18 for stretch in leaflet material on closure of the
19 valve.

20
21 Preferably a correction factor is used to compensate
22 for movement in the notional point of coincidence of
23 the leaflets.

24
25 Preferably the first wave is asymmetric about the
26 vertical mid plane parallel to and intersecting the
27 blood flow axis of the leaflets.

28
29 Preferably the composite wave is asymmetric about
30 the vertical mid plane parallel to and intersecting
31 the blood flow axis of the leaflets.

32

1 Preferably the valve comprises three leaflets.

2

3 Preferably the frame has first and second ends, the
4 first end defining at least three scalloped edge
5 portions separated by at least three posts, each
6 leaflet attached to the frame along a corresponding
7 scalloped edge portion.

8

9 Preferably the three posts are rotationally
10 symmetrically distributed around the circumference
11 of the frame.

12

13 Preferably the frame is a collapsible stent.

14

15 Preferably the collapsible stent can be delivered to
16 the patient by percutaneous delivery.

17

18 More preferably the collapsible stent can be moved
19 from a collapsed to an erect position using an
20 inflatable balloon when the stent is suitably
21 located in the patient.

22

23 According to a second aspect of the invention there
24 is a method of making a cardiac valve prosthesis
25 wherein the method comprises;

26

27 - providing a forming element having at least
28 two leaflet-forming surfaces wherein the
29 forming surfaces are such that the length in
30 the circumferential direction (XY) of the
31 leaflet-forming surface is defined by a
32 parabolic function,

1 - engaging the forming element with the frame,
2 - applying a coating over the frame and the
3 engaged forming element, the coating binding to
4 the frame, the coating over the leaflet-forming
5 surfaces forming at least two flexible
6 leaflets, the at least two flexible leaflets
7 having a length in the circumferential
8 direction (XY) defined by a parabolic function
9 and a surface contour such that when the first
10 leaflet is in the neutral position an
11 intersection of the first leaflet with at least
12 one plane perpendicular to the blood flow axis
13 forms a first wave having a first frequency,
14 - disengaging the frame from the forming
15 element.

16
17 The leaflets are in a neutral position intermediate
18 to the open and closed position in the absence of
19 fluid pressure being applied to the leaflets.

20
21 Preferably there is provided a method of making a
22 cardiac valve prosthesis wherein the method
23 comprises;

24
25 - providing a forming element having at least
26 two leaflet-forming surfaces wherein the
27 forming surfaces are such that the length in
28 the circumferential direction (XY) of the
29 leaflet-forming surface is defined by a
30 parabolic function,
31 - engaging the forming element with the frame,

- 1 - applying a coating over the frame and the
- 2 engaged forming element, the coating binding to
- 3 the frame, the coating over the leaflet-forming
- 4 surfaces forming at least two flexible
- 5 leaflets, the at least two flexible leaflets
- 6 having a length in the circumferential
- 7 direction (XY) defined by a parabolic function
- 8 and a surface contour such that when the first
- 9 leaflet is in the neutral position an
- 10 intersection of the first leaflet with at least
- 11 one plane perpendicular to the blood flow axis
- 12 forms a composite wave defined by at least two
- 13 waves of differing frequency,
- 14 - disengaging the frame from the forming
- 15 element.
- 16
- 17 Preferably there is provided a method of making a
- 18 cardiac valve prosthesis wherein the method
- 19 comprises;
- 20
- 21 - providing a forming element having three
- 22 leaflet-forming surfaces wherein the forming
- 23 surfaces are such that the length in the
- 24 circumferential direction (XY) of the
- 25 leaflet-forming surface is defined by a
- 26 parabolic function,
- 27 - engaging the forming element with the frame,
- 28 - applying a coating over the frame and the
- 29 engaged forming element, the coating binding to
- 30 the frame, the coating over the leaflet-forming
- 31 surfaces forming three flexible leaflets, the
- 32 three flexible leaflets each having a length in

1 the circumferential direction (XY) defined by a
2 parabolic function and a surface contour such
3 that when the first leaflet is in the neutral
4 position an intersection of the first leaflet
5 with at least one plane perpendicular to the
6 blood flow axis forms a wave defined by at
7 least a first wave, having a first frequency,
8 - disengaging the frame from the forming
9 element.

10

11 Preferably there is provided a method of making a
12 cardiac valve prosthesis wherein the method
13 comprises;

14 - providing a forming element having three
15 leaflet-forming surfaces wherein the forming
16 surfaces are such that the length in the
17 circumferential direction (XY) of the leaflet-
18 forming surface is defined by a parabolic
19 function,
20 - engaging the forming element with the frame,
21 - applying a coating over the frame and the
22 engaged forming element, the coating binding to
23 the frame, the coating over the leaflet forming
24 surfaces forming three flexible leaflets, the
25 three flexible leaflets each having a length in
26 the circumferential direction (XY) defined by a
27 parabolic function and a surface contour such
28 that when the first leaflet is in the neutral
29 position an intersection of the first leaflet
30 with at least one plane perpendicular to the
31 blood flow axis forms a composite wave defined
32 by at least two waves of differing frequency,

1 - disengaging the frame from the forming
2 element.

3

4 It will be appreciated by those skilled in the art
5 that leaflets of appropriate lengths and shape can
6 be formed using dip moulding, conventional injection
7 moulding, reaction injection moulding or compression
8 moulding.

9

10 Preferably the method further comprises trimming the
11 free edge of at least one leaflet.

12

13 More preferably the method further comprises
14 trimming the free edge of at least one leaflet in
15 the longitudinal direction (Z) of the leaflet.

16

17 More preferably the free edge of the leaflet is
18 trimmed such that in the longitudinal direction (Z)
19 the free edge of at least one leaflet is parabolic.

20

21 Preferably the free edge of at least one leaflet is
22 parabolic in the longitudinal direction toward the
23 second end of the frame such that the maximum depth
24 of the parabolic cut is between 50 μ m to 1000 μ m lower
25 than the notional free edge of the leaflet.

26

27 The leaflet has a top and bottom, the bottom of the
28 leaflet being attached to the scalloped portion.

29

30 The top of the leaflet may extend beyond the tip of
31 the posts of the frame e.g. by up to 1500 μ m from
32 the tip of the posts.

1

2 The notional free edge is defined as the free edge
3 of the leaflet prior to trimming. The notional free
4 edge may extend between the posts at a longitudinal
5 height of between 0 to 1500 μm from the tip of the
6 posts.

7

8 Preferably at least one leaflet has different
9 thicknesses along a cross section defined by the
10 intersection of a plane perpendicular to the blood
11 flow axis.

12

13 More preferably the thickness of the cross section
14 of at least one leaflet in the XY plane, defined by
15 the intersection of a plane perpendicular to the
16 blood flow axis, changes gradually and substantially
17 continuously from a thickest portion where the
18 leaflet is conjoined to the frame to a thinnest
19 portion at the midpoint of the XY plane of the
20 leaflet.

21

22 A problem associated with the design of synthetic
23 heart valves is that changing the diameter of the
24 valve or height of the posts of the frame affects
25 the calculation of leaflet geometry. In order to
26 overcome the effects of valve diameter or post
27 heights on leaflet geometry, geometric scaling is
28 typically employed.

29

30 Preferably the functions described herein can be
31 used irrespective of valve diameter or the height of
32 the posts of the frame, to obtain suitable leaflet

1 geometry and does not require the use of geometric
2 scaling.

3
4 Therefore functions disclosed by the present
5 Application which describe length in the
6 circumferential direction (XY) of a leaflet e.g. the
7 leaflet geometry optimised for a 27mm inside
8 diameter of stent can be used to describe the length
9 in the circumferential direction (XY) leaflet
10 geometry for a stent of different diameter e.g. 17mm
11 inside diameter stent.

12
13 This makes the design and manufacture of valves of
14 different diameters more convenient.

15
16 An embodiment of the present invention will now be
17 described, by way of example only with reference to
18 the accompanying drawings wherein;

19
20 Figure 1 is a plan view of a trileaflet heart
21 valve in the closed position;

22
23 Figure 2a is a perspective view of an
24 embodiment of a trileaflet heart valve of the
25 present invention in a semi-closed position;

26
27 Figure 2b is a perspective view of a prior art
28 trileaflet heart valve in a semi-closed
29 position;

30

1 Figure 3 is a plan view of an embodiment of a
2 trileaflet heart valve of the present invention
3 in a semi-closed position;

4

5 Figure 4a is a plan view of a prior art
6 trileaflet heart valve in a fully open
7 position;

8

9 Figure 4b is a plan view of a prior art
10 trileaflet heart valve as shown in figure 4a in
11 a fully closed position;

12

13 Figure 4c is a plan view of an embodiment of a
14 trileaflet heart valve according to the present
15 invention in a fully open position;

16

17 Figure 4d is a plan view of an embodiment of a
18 trileaflet heart valve according to the present
19 invention as shown in figure 4c in a fully
20 closed position;

21

22 Figure 5a is a cross section of the valve as
23 shown in figure 2a along line 3-3;

24

25 Figure 5b is a cross section of the prior art
26 valve as shown in figure 2b along line 3-3;

27

28 Figure 6 is a plan view illustration of an
29 embodiment of a trileaflet heart valve of the
30 present invention;

31

- 1 Figure 7a shows a partial cross section of a
2 post of an embodiment of a trileaflet heart
3 valve of the present invention in the open
4 position (II) and the closed position (I) of
5 the valve;
6
7 Figure 7b shows the a partial cross section of
8 an embodiment of a leaflet of the present
9 invention along the vertical midplane in the
10 open position (II) and closed position (I) of
11 the valve;
12
13 Figure 7c shows the a partial cross section of
14 a post of a prior art valve in the open
15 position (II) and closed position (I) of the
16 valve;
17
18 Figure 7d shows the a partial cross section of
19 a leaflet of a prior art valve along the
20 vertical midplane in the open (II) and closed
21 (I) position of the valve;
22
23 Figure 8a shows the principal stress envelope
24 present in a prior art heart valve leaflet;
25
26 Figure 8b shows the strain energy release
27 present in a prior art heart valve leaflet in
28 the X axis from a closed to open position;
29
30 Figure 8c shows the strain energy release
31 present in a prior art heart valve leaflet in
32 the Y axis from a closed to open position;

1

2 Figure 8d shows the resultant strain energy
3 release present in a prior art heart valve
4 during cycling from a closed to open position;

5

6 Figure 9a shows the principal stress envelope
7 present in an embodiment of a heart valve
8 according to the present invention;

9

10 Figure 9b shows the strain energy release
11 present in an embodiment of a heart valve
12 according to the present invention in the X
13 axis from a closed to open position;

14

15 Figure 9c shows the strain energy release
16 present in an embodiment of a heart valve
17 leaflet according to the present invention in
18 the Y axis from a closed to open position;

19

20 Figure 9d shows the resultant strain energy
21 release present in an embodiment of a heart
22 valve leaflet according to the present
23 invention during cycling from a closed to open
24 position;

25

26 Figure 10 is an illustration of an embodiment
27 of one leaflet according to the present
28 invention;

29

30 Figure 11 is a diagrammatic representation of a
31 prior art leaflet moving from a semi-closed (a)
32 to successively more open position (b) and (c)

1 to a fully open position (d) illustrating the
2 formation of a bubble or buckle;
3

4 Figure 12 illustrates the shape of the leaflet
5 being defined by a first wave further to
6 determination of the circumferential length of
7 the leaflet; and
8

9 Figure 13 is graph of Cardiac Output (l/min)
10 against mean Pressure Gradient (mmHg).
11

12 As previously discussed, a number of designs have
13 been suggested for use in cardiac heart valves to
14 ensure that the heart valves have sufficient leaflet
15 material such that the valve is capable of opening
16 as wide as possible to the maximum orifice of the
17 valve, and that such opening requires as little
18 energy as possible and further that regurgitation of
19 blood through the valve is minimised.
20

21 In order to minimise the regurgitation of blood it
22 has been suggested that the free edge of the valve
23 is spherical in geometry to ensure that the free
24 leaflet edges are able to come together and seal
25 against one another.
26

27 US Patent 5,500,016 discloses a leaflet defined by
28 the equation:
29

30
$$z^2 + y^2 = 2RL(x-g) - \alpha(x-g)^2$$

31

1 to describe the geometry of the leaflets. As Z,
2 defines the shape of the leaflet in the blood flow
3 axis and as Z is defined as z^2 then a leaflet
4 defined by the above would have a spherical geometry
5 in the axis parallel to blood flow. International
6 Patent Application WO 98/32400 discloses that
7 spherical surfaces at the leaflet edges seal more
8 effectively than planar or conical surfaces.
9 International Application WO 01/41679 discloses that
10 stresses are highest in the region of the commissures
11 where loads are transmitted to the stent, but they
12 are reduced when the belly of the leaflet is as low
13 as practicable in the closed valve.

14
15 In addition International Application WO 98/32400
16 also suggests that it is advantageous to provide a
17 spherical portion of leaflet adjacent to the base of
18 the leaflet as it confers advantages in the stress
19 distribution when the valve is closed and pressure
20 is greater downstream than upstream.

21
22 The prior art teaches that leaflets of heart valves
23 should have considerable excess material in the
24 vertical axis Z, parallel to the blood flow to
25 enable a suitable seal to be achieved at the free
26 edge of the leaflet and to reduce the stress present
27 in the leaflet during open and closing.

28
29 As shown in figure 1 and figure 2a, a preferred
30 embodiment of the heart valve prosthesis 8 of the
31 present invention comprises a stent or frame 10
32 which is substantially cylindrical. The frame has a

1 first end 12 and second end 14. The first end 12
2 comprises three scalloped edge portions 16a, 16b and
3 16c separated by three posts 18, each post having a
4 tip 20. The cardiac valve further comprises three
5 leaflets 30. Each leaflet 30 has a fixed edge 32
6 joined to a respective scalloped edge 16a, 16b or
7 16c of the frame 10 and a free edge 34 which extends
8 substantially between the tips 20 of the posts 18.
9

10 The leaflets 30 are configured to be movable from an
11 open to a closed position and from a closed to open
12 position. In an aortic position (when the
13 prosthesis is positioned at the site of the aortic
14 valve), the leaflets 30 have a blood inlet side 36
15 and a blood outlet side 38 and are in the closed
16 position when fluid pressure is applied to the
17 outlet side 38 i.e. by the blood of the aortic
18 artery and in the open position when fluid pressure
19 is applied to the inlet side 36 i.e. by the blood of
20 the ventricle. The leaflets are in a neutral
21 position intermediate to the open and closed
22 position in the absence of fluid pressure being
23 applied to the leaflets.
24

25 Where the valve is being used in a mitral position,
26 between the left atrium and left ventricle of the
27 heart, the orientation of the valve is the opposite
28 to that described above such that blood flow from
29 the left atrium moves the leaflets to an open
30 position, the leaflets opening towards the left
31 ventricle to allow blood to flow into the left
32 ventricle. Back pressure from blood flow from the

1 left ventricle towards the left atrium causes the
2 mitral valve to close to minimise regurgitation.

3

4 In figure 5b which is a sectional view along line 3-
5 3 illustrating the closed position of a leaflet of a
6 valve of the prior art, a 'belly' portion 40 exists
7 in the mid portion of the leaflet. This 'belly'
8 portion between the free edge and the central
9 portion of the leaflet causes leaflets of the prior
10 art to have a double curvature, a curve in XY and a
11 curve in Z. Further, the 'belly' shape 40 causes
12 leaflets of the prior art to be almost concave in
13 shape when viewed in cross section along the
14 vertical midplane of the leaflet.

15

16 As shown in figure 5a which is a sectional view of
17 the valve of the present invention along line 3-3 as
18 shown in figure 2a, no 'belly' is present in the
19 leaflets and in Z the leaflet in the closed position
20 is substantially linear.

21

22 The prior art design including a 'belly' portion was
23 favoured as it was thought to maximise sealing of
24 the valve at the free edge and minimise
25 regurgitation.

26

27 However, the double curvature, which comprises
28 curvature in XY plane and in Z plane results in
29 excess leaflet material at both the open and closed
30 position which promotes the formation of a bubble or
31 buckle 50 in the leaflet material (as shown in

1 figure 11) during movement from a closed to open
2 position.

3

4 This excess material is shown most clearly by
5 comparing figure 7d which shows a cross section of
6 the valve along the vertical midplane (line I-I of
7 figure 2b) of the leaflet 30 parallel to the blood
8 flow axis. in a prior art leaflet with figure 7b
9 which shows a cross section along the vertical
10 midplane (line I-I of figure 2a) of a leaflet of the
11 present invention. This comparison clearly shows
12 that the leaflet 30 of the present Application does
13 not display a belly region 40. Indeed the cross
14 section shown in figure 7b indicates that the
15 leaflet shape of the present invention is
16 substantially linear in the vertical direction in
17 both the open and closed valve positions.

18

19 To determine the circumferential length of material
20 in XY to remove the 'belly' 40 observed in prior art
21 leaflets, the length in the circumferential
22 direction (XY) of the leaflet for any position in z
23 must be determined, which still allows suitable
24 opening and closure of the valve.

25

26 As shown in figure 6 the material of the leaflet
27 must extend between the posts 18 such that in a
28 closed position the free edge of the leaflets 34
29 come together at point 42 to minimise regurgitation
30 of blood through the valve.

31

1 This circumferential length (XY) can be
2 mathematically defined using a parabolic function.

3

4 Function of a parabola

$$5 \quad Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$$

6

7 Wherein $Y_z = Y$ offset at a particular co-ordinate X
8 and Z

9 $R =$ parabolic maximum

10 $L_z =$ straight line distance between a
11 first post and a second post of the frame
12 at a height Z

13 $X =$ distance from origin of post towards
14 another post

15

16 To calculate the circumferential length (XY) at a
17 height point of the posts for a leaflet defined in
18 the circumferential (XY) direction by a parabolic
19 function the following function can be used:

20

$$21 \quad \text{length of parabolic curve} = \int_0^L \sqrt{1 + \left(\frac{dy}{dx} \right)^2} dx$$

22

23 This allows a circumferential length (XY) to be
24 determined at each height point in Z.

25

26 Thus as shown in figure 10 the circumferential
27 length (XY) can be determined at $Z_1, Z_2, Z_3 \dots Z_n$.

28

1 The length of the leaflet in the circumferential
2 direction (XY) is calculated and repeated in the
3 radial direction (Z) to provide the complete
4 geometry of the leaflet.

5
6 As the scallop edge 32 of the frame 10 as defined by
7 the posts 18 of the frame is known, then a leaflet
8 30 can be defined by determining the distance
9 between the two posts 18 at several height points in
10 Z (where Z is a particular height along the posts).
11 This post to post distance can then be used in the
12 equation detailed above to generate a parabola (P)
13 at each height point. Due to the scallop shape 32
14 defined by the posts 18 the circumferential length
15 of the leaflet in XY will decrease moving from the
16 first end at the tip 20 of the posts toward the
17 second end of the frame 14 at the base of the posts.
18 The more height points which are chosen, the more
19 lengths (P) can be calculated along Z. If a large
20 number of height points are chosen the lengths
21 determined by the parabolic function moving from the
22 tip of the posts to the base will vary in a
23 substantially linear fashion.

24
25 The leaflets 30 of a valve 8 which are of
26 circumferential length (XY) as determined using the
27 above parabolic function will meet at the free edge
28 34 of the leaflet 30, but will not meet
29 significantly at points lower than the free edge 34.
30 The meeting of the leaflets at the free edge allows
31 regurgitation to be minimised without including

1 excess material or a belly region 40 in the leaflets
2 30.

3
4 The circumferential length (XY) can be further
5 adjusted to take account of factors which occur
6 during cycling of the heart valve. These factors
7 include inward movement of the posts 18 of the frame
8 10 due to pressure on the leaflets 30 during closing
9 of the valve. The amount of inward movement of the
10 posts 18 of the frame 10 is influenced by the
11 rigidity of the frame 10 and the pressure exerted on
12 the valve. The tips 20 of the posts 18 of the frame
13 10 move to a greater extent than the base of the
14 posts and as the scallop geometry between the posts
15 18 of the frame 10 is accurately known this
16 differential movement can be taken into account when
17 determining the optimal circumferential length (P)
18 of XY in the leaflet 30.

19
20 In addition to the posts 18 of the frame 10 moving
21 toward each other during closure, the posts 18 also
22 move towards the centre point 42 where the leaflets
23 meet or the point of coincidence. The
24 circumferential length XY of the leaflet can be
25 adjusted to account for this movement.

26
27 The material of the leaflet 30 typically has some
28 degree of elasticity and will stretch in response to
29 blood flow pressure. This stretching can again be
30 taken into account in determining the lengths of the
31 leaflet 30 to ensure that a belly region 40 of the
32 valve is minimised.

1
2 As shown in figure 8a, analysis of the stresses over
3 time incurred by heart valves during the cycling
4 process has revealed that the principal area of
5 stress 60 in existing cardiac valves is found close
6 to the midpoint of the free edge of the leaflets.
7

8 Using the data from figure 8a, strain energy release
9 in X and Y, as shown in figures 8b and 8c
10 respectively can be determined. Figure 8b shows
11 that leaflets of the prior art have a vertical
12 predisposition to defect propagation 62 at the free
13 edge 34. Figure 8c indicates that leaflets have a
14 predisposition to defect in the lateral dimension,
15 at an area 64 in the leaflet 30 lower than the free
16 edge of the leaflet 34, the lower area being located
17 above the central portion of the leaflet. In tests
18 during cycling of cardiac valves it has been found
19 that over time, the stress in this lower area
20 promotes failure of defects in the material to
21 occur. These defects can cause valve failure.
22

23 The present invention has shown that analysis of the
24 dynamics of existing valves during the cycling
25 process has determined that the stress in this lower
26 area is caused by the leaflets requiring to change
27 the direction of their surface curvature during
28 cycling.
29

30 In particular, as shown in figure 11, on cycling
31 from a closed to an open position a region lower
32 than the free edge forms a bubble like formation or

1 buckle 50 on the surface of the leaflet which is
2 opposite in direction to the curvature of the
3 surface of the rest of the leaflet.

4
5 On moving from the closed to open position the
6 bubble like formation 50 is forced to become
7 inverted such that it projects in an opposite
8 direction causing a whip like action in the leaflet
9 30. This whip like action promotes high stresses in
10 the area lower than the free edge 34 of the leaflet,
11 as shown in figures 8a, 8b, 8c and 8d.

12
13 The inventor has surprisingly determined, as shown
14 in figure 9a, that the principal stress envelope in
15 relation to the valve as described in the present
16 application, wherein the circumferential length XY
17 of the leaflet at any point in Z is defined as a
18 parabolic function, is decreased across the whole of
19 the valve. In particular strain energy release in X
20 and Y, as shown in figures 9b and 9c respectively,
21 in relation to the valve of the present invention
22 indicates that a leaflet wherein the circumferential
23 lengths XY are determined by a parabolic function
24 has minimised predisposition to defect propagation
25 in the lateral dimension at an area in the leaflet
26 lower than the free edge of the leaflet and above
27 the central portion.

28
29 A reduction in the predisposition to defect
30 propagation in the lateral dimension at an area in
31 the leaflet between the free edge of the leaflet and
32 the central portion in the leaflet of the present

1 invention is observed because there is less excess
2 material and thus minimal belly in the leaflet of
3 the present design.
4

5 On moving from the closed to open position a bubble
6 like formation 50 is no longer created and thus a
7 whip like action does not occur in the leaflet. As
8 discussed, it is this whip like action which has
9 been determined to promote high stresses in the area
10 lower than the free edge of the leaflet. As
11 illustrated by comparing figures 8a and 9a, in
12 contrast to the valves of the prior art, uniform
13 principle stress distribution, is observed across
14 the surface of the leaflet of the valve described in
15 the present Application.
16

17 Minimisation of the regions of stress in the
18 leaflet, during cycling of the leaflet, will
19 increase the durability of the leaflet.
20

21 Use of a parabolic function to determine the
22 circumferential lengths XY of the leaflet at each
23 height point in Z causes the vertical distribution
24 of lengths of the leaflet to be substantially linear
25 at the fully open and closed position.
26

27 It will be appreciated by those in the art that
28 other functions with the addition of suitable
29 modifying factors could be used to derive a function
30 which substantially describes a parabola and which
31 leads to the vertical distribution of lengths of the
32 leaflet to be substantially linear at the fully open

1 and closed position, but which is based on for
2 instance an elliptical function.

3
4 As discussed, additional parameters may be included
5 in the parabolic function used to determine the
6 circumferential lengths XY of the leaflet. These
7 additional factors may account for movement in the
8 posts of the stent, elasticity of the leaflet
9 material during movement of the leaflets from a
10 closed to an open position or other factors which
11 occur during cycling which influence the length of
12 the leaflet require to allow closure.

13
14 The function described above explicitly determines
15 lateral lengths of the parabolic curve at any height
16 point in Z which is along a post of the frame. In
17 view of this the above function can be applied to
18 any diameter of valve or valves with different
19 heights of posts, without the need for geometric
20 scaling. This means that different dimensions of
21 valves can be manufactured with the same leaflet
22 geometry without further undue experimentation.

23
24 The surface contour of the leaflets 30 of the
25 embodiment described are such that in a fully open
26 position, the intersection of the leaflets of the
27 valve perpendicular to the blood flow axis, forms a
28 substantially cylindrical shape.

29
30 In addition to the above, it has also been
31 determined that stress at the free edge of the
32 leaflet, as shown in figure 8a, can be further

1 reduced by trimming the free edge 34 of the leaflet
2 in the longitudinal direction (Z) such that the free
3 edge is substantially parabolic 70, with the maximum
4 depth of the parabola being furthest from the
5 notional untrimmed free edge 74. The maximum depth
6 of the parabola is generally located at the midpoint
7 of the free edge 72 (figure 9a). Figure 9a shows
8 the effect of introducing a parabolic curve in the
9 vertical direction of the free edge. Comparison of
10 figures 8b, 8c and 8d with 9b, 9c and 9d shows that
11 the strain energy release at the free edge is
12 significantly reduced through the introduction of
13 the parabola in the longitudinal direction (Z).
14

15 Ideally the notional free edge 74 is trimmed in a
16 parabolic curve, wherein the maximum depth 72 of the
17 parabola 70 is between 50 μ m to 1000 μ m lower than the
18 notional untrimmed free edge 74.
19

20 A different shape of cut, trim or notch can be
21 introduced in the free edge to decrease the stress
22 at the free edge. However, particular shapes of
23 cuts, trims or notches may introduce defects into
24 the leaflet which would decrease the leaflets
25 durability to stress. A parabolic trim as described
26 is therefore advantageous in that focal points of
27 stress are not introduced to the free edge of the
28 leaflet.
29

30 Leaflets of the geometry described herein can be
31 produced using methods known in the art such as

1 injection moulding, reaction injection moulding,
2 compression moulding or dip moulding.

3
4 As discussed the circumferential length XY of the
5 leaflet at any height point in Z along the post of
6 the frame is explicitly provided by the function
7 described above. On determining the length of the
8 leaflet at each point in Z to minimise the formation
9 of a belly in the leaflet, the shape of the leaflet
10 in the circumferential direction can be defined by
11 at least one wave 80. As shown in figure 12,
12 further to determining the circumferential length
13 determined at a chosen point in Z and applying
14 appropriate correction factors to determine a final
15 XY length at that point in Z, the shape of the
16 leaflet is then defined as a wave.

17
18 As shown in figure 13, surprisingly, in addition to
19 reducing the lateral stress of the valve,
20 determination of the length of the leaflet at each
21 point in Z according to a parabolic function not
22 only minimises the formation of a belly in the
23 leaflet, but also reduces the pressure gradient
24 required to open the valve from a closed position.

25
26 The opening of a cardiac valve to as wide an orifice
27 as possible under minimal pressure gradients is a
28 key parameter in the design of synthetic heart
29 valves.

30
31 The valve is produced such that in a cast position
32 the leaflet is in neutral position, intermediate the

1 open and closed position in the absence of fluid
2 pressure being applied to the leaflets. Production
3 of the valve in the neutral position means that the
4 leaflets are substantially free of bending stresses
5 in this position.

6

7 The shape of the former on which the leaflet is
8 formed is defined by either at least one wave or
9 several waves which form a composite wave.

10

11 Regardless of the shape of the leaflet, the length
12 of the leaflet is defined at each point in Z along
13 the post of the scallop by a parabolic function as
14 described above together with any correction
15 factors.

16

17 The shape of the inner surface of the leaflets will
18 substantially replicate the shape of the former.
19 The shape of the outer surface of the leaflets will
20 be similar to the shape of the inner surface, but
21 variations will result e.g. from the properties of
22 the polymer solution and techniques used to create
23 the leaflet.

24

25 The leaflets of suitable length as defined by the
26 parabolic function and any correction factors and of
27 shape as defined by either a single or composite
28 wave function are attached to a suitable frame. The
29 construction of a suitable frame will be obvious to
30 those skilled in the art. The frame can be made of
31 a biocompatible polymer, metal or composite. The

1 frame can be coated with polyurethane to allow
2 integration of the leaflets.

3

4 Further to describing a first leaflet using the
5 above function, the remaining two leaflets of this
6 three leaflet embodiment can be determined by
7 rotating the geometry about the Z axis through 120°
8 and then through 240° .

9

10 Having formed the leaflets of the valve as described
11 above these can then be trimmed such that the edge
12 of the leaflet not attached to the frame extends
13 horizontally between two posts horizontally between
14 a longitudinal length 0 to $1500\mu\text{m}$ beyond the tips of
15 the posts of the frame. The edge of the leaflets
16 which extends horizontally between the tips of the
17 posts or between a longitudinal length 0 to $1500\mu\text{m}$
18 beyond the tip of the posts is deemed to be the
19 notional free edge of the leaflets.

20

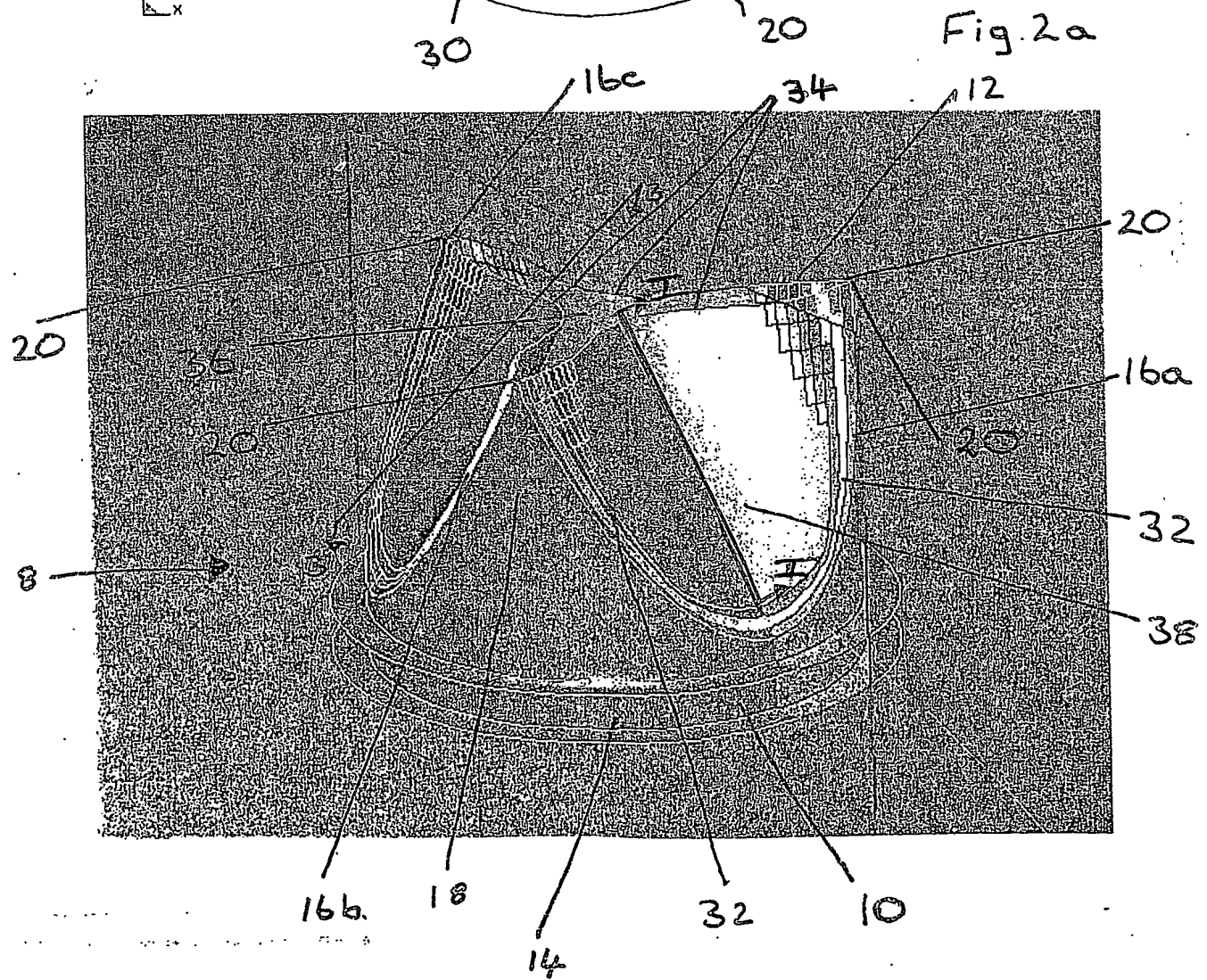
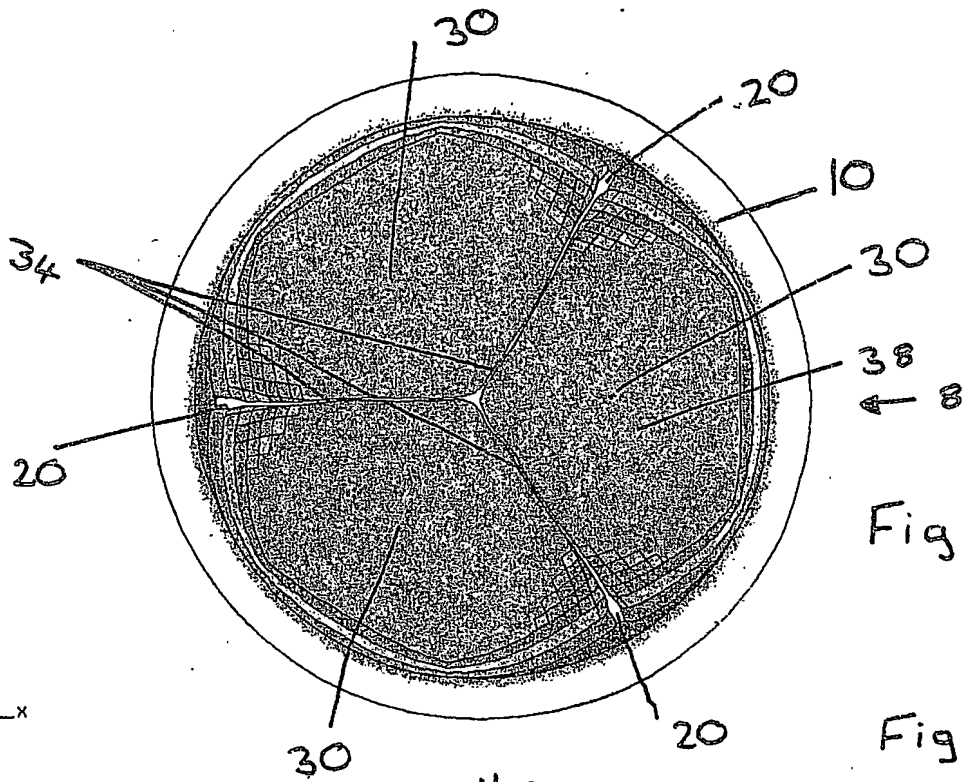
21 The notional free edge of the leaflet can be further
22 trimmed in the longitudinal direction such that a
23 parabolic curve is introduced, the maximum depth of
24 the parabola being located between $50\mu\text{m}$ to $1000\mu\text{m}$
25 opposite the notional untrimmed free edge toward the
26 portion of the leaflet which attaches the leaflet to
27 the scallop portion of the frame.

28

29 A valve of the present invention may be used in any
30 required position within the heart to control blood

- 1 flow in one direction, or to control flow within any
- 2 type of cardiac assist device.
- 3
- 4 Modifications and improvements can be incorporated
- 5 without departing from the scope of the invention.

1/15



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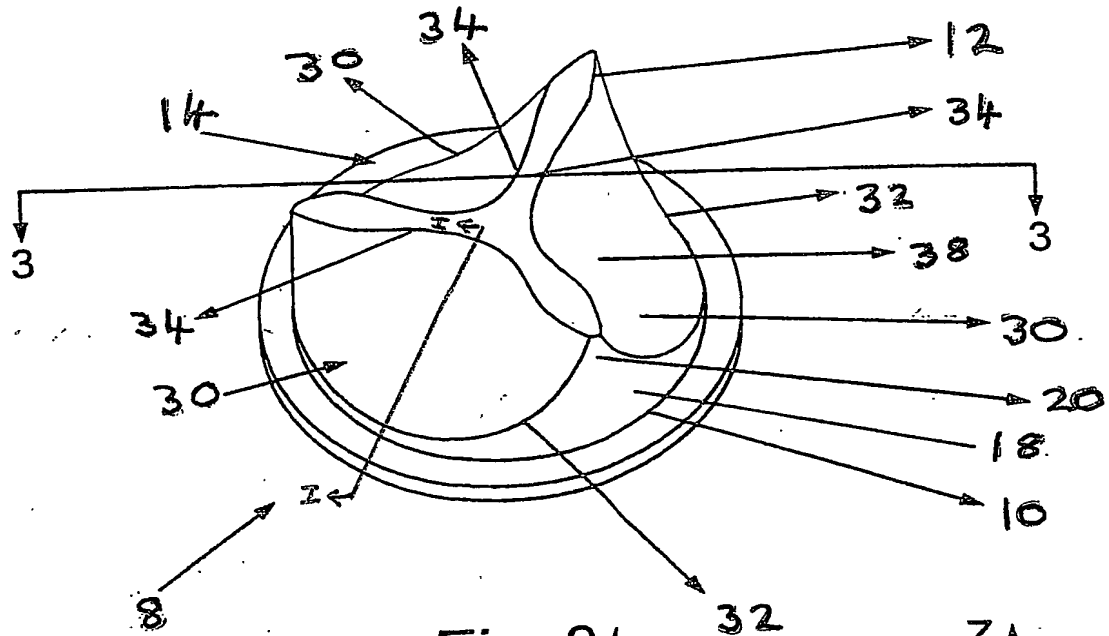
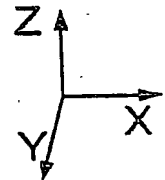
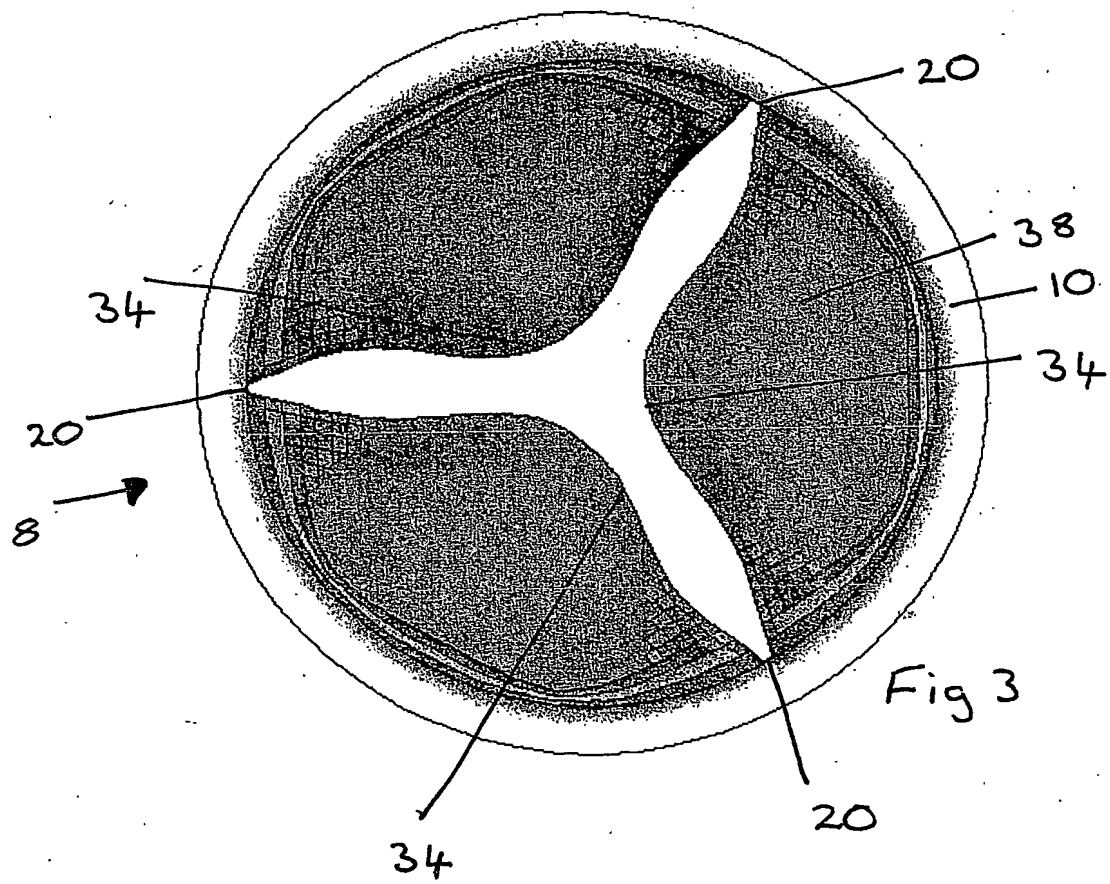
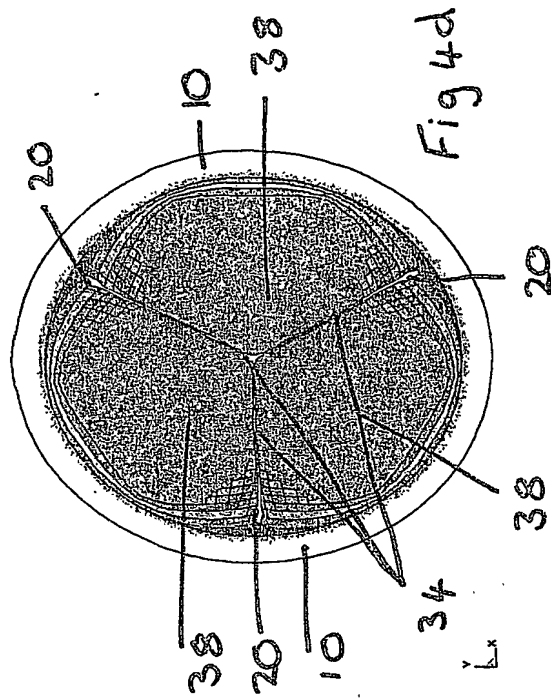
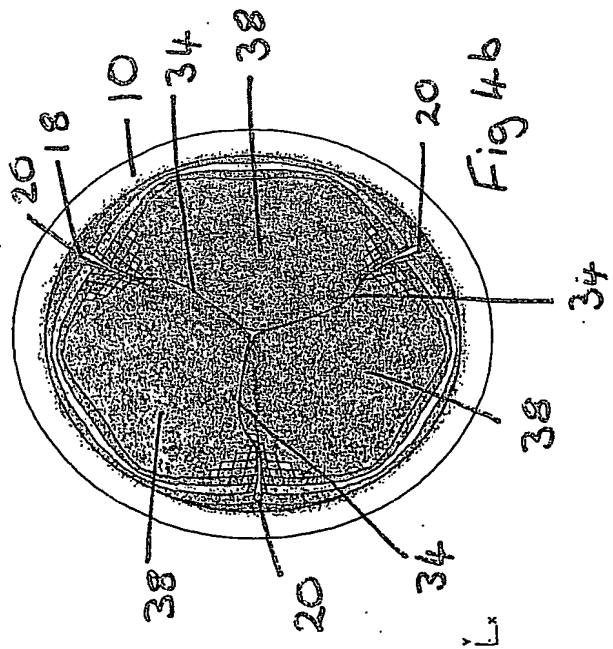
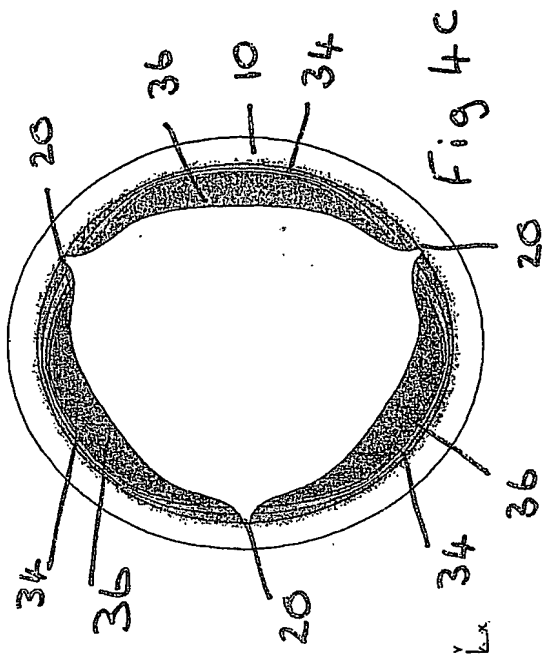
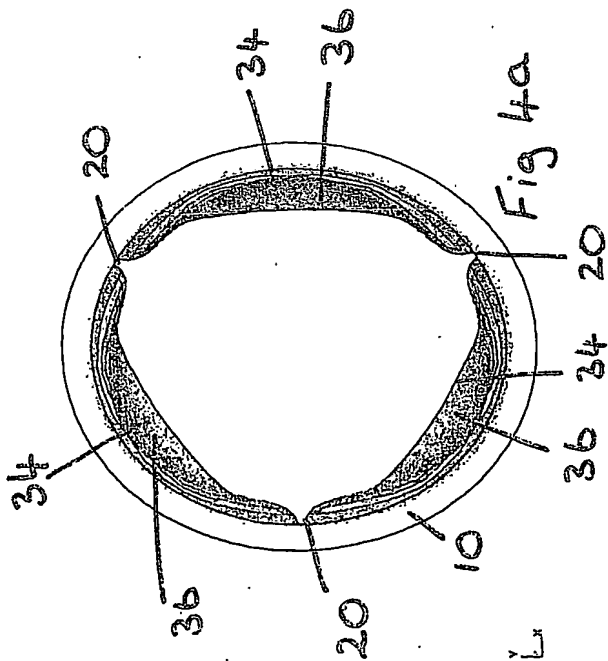


Fig. 2b.

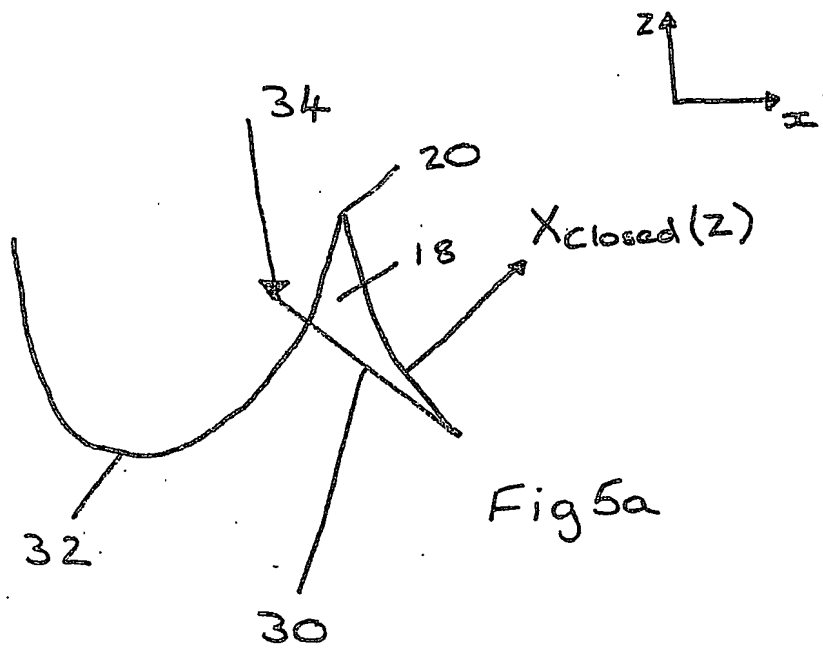


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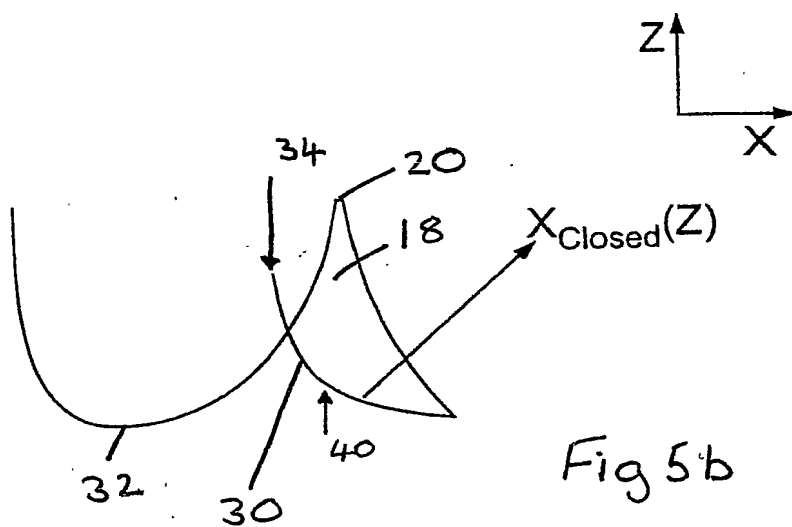


Fig 5b

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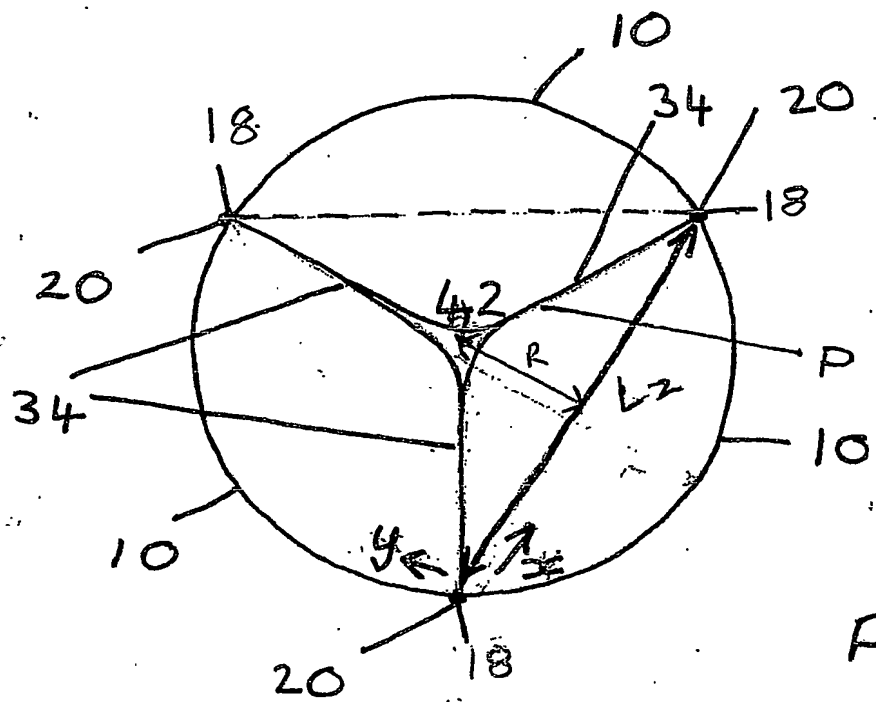


Fig 6

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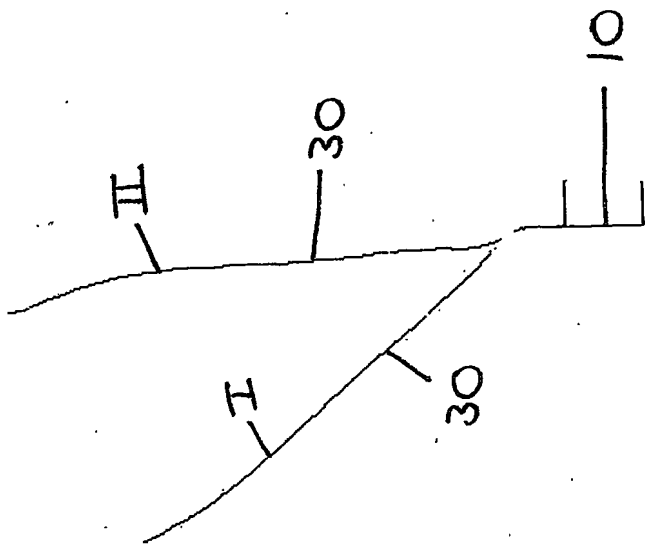


Fig 7b

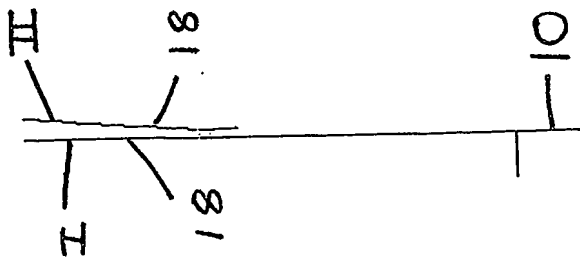


Fig 7a

z
x

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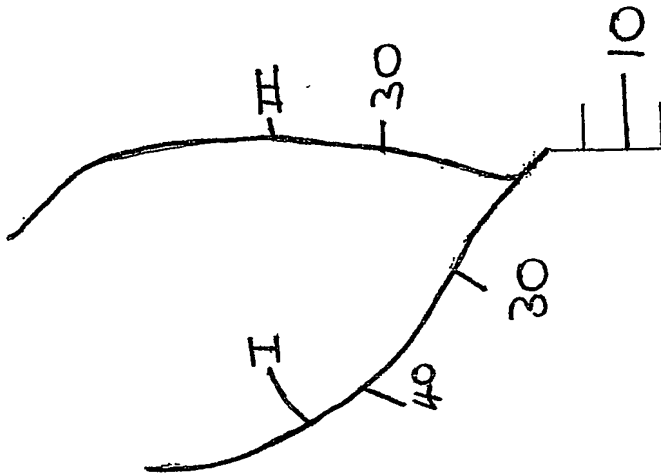


Fig 7d

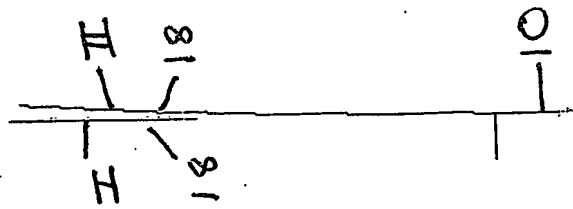
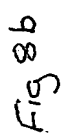
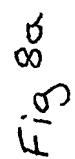
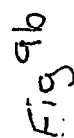
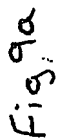
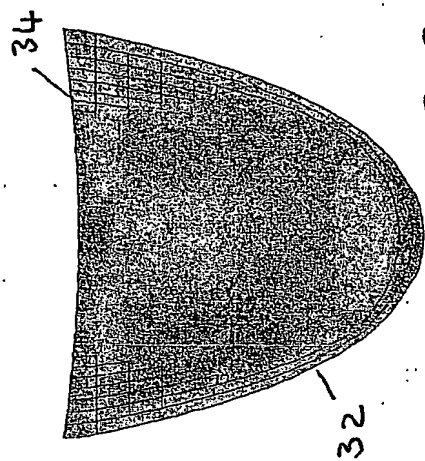


Fig 7c

z
x





592

z-y

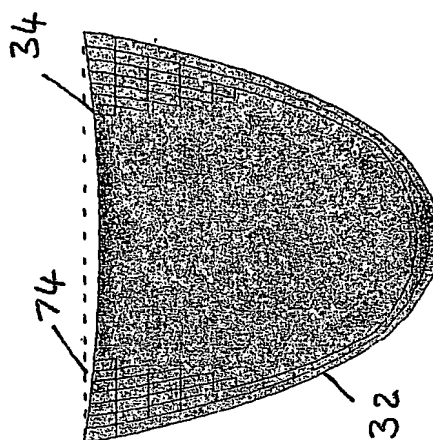
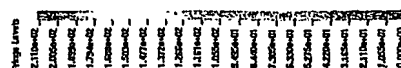
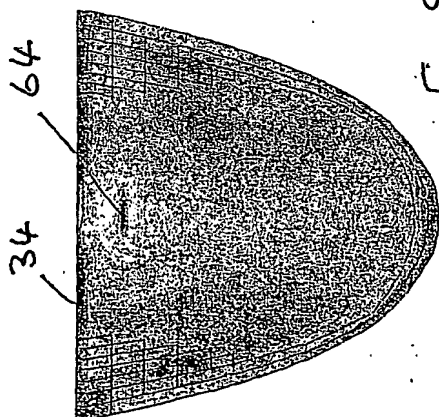
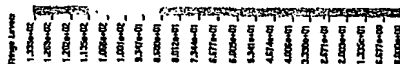


Fig. 90

$$Z_{\text{eff}}$$


۵۵

z
y

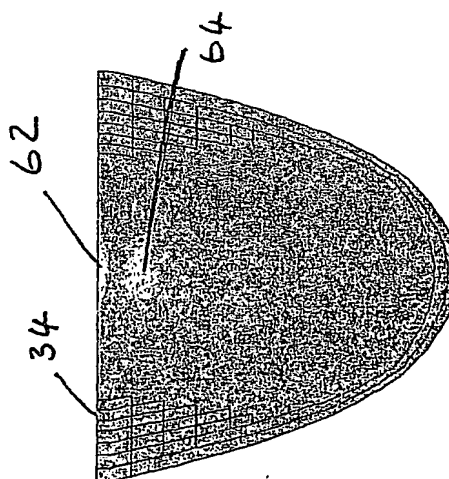
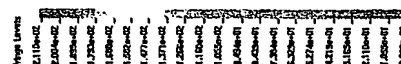


Fig 8d

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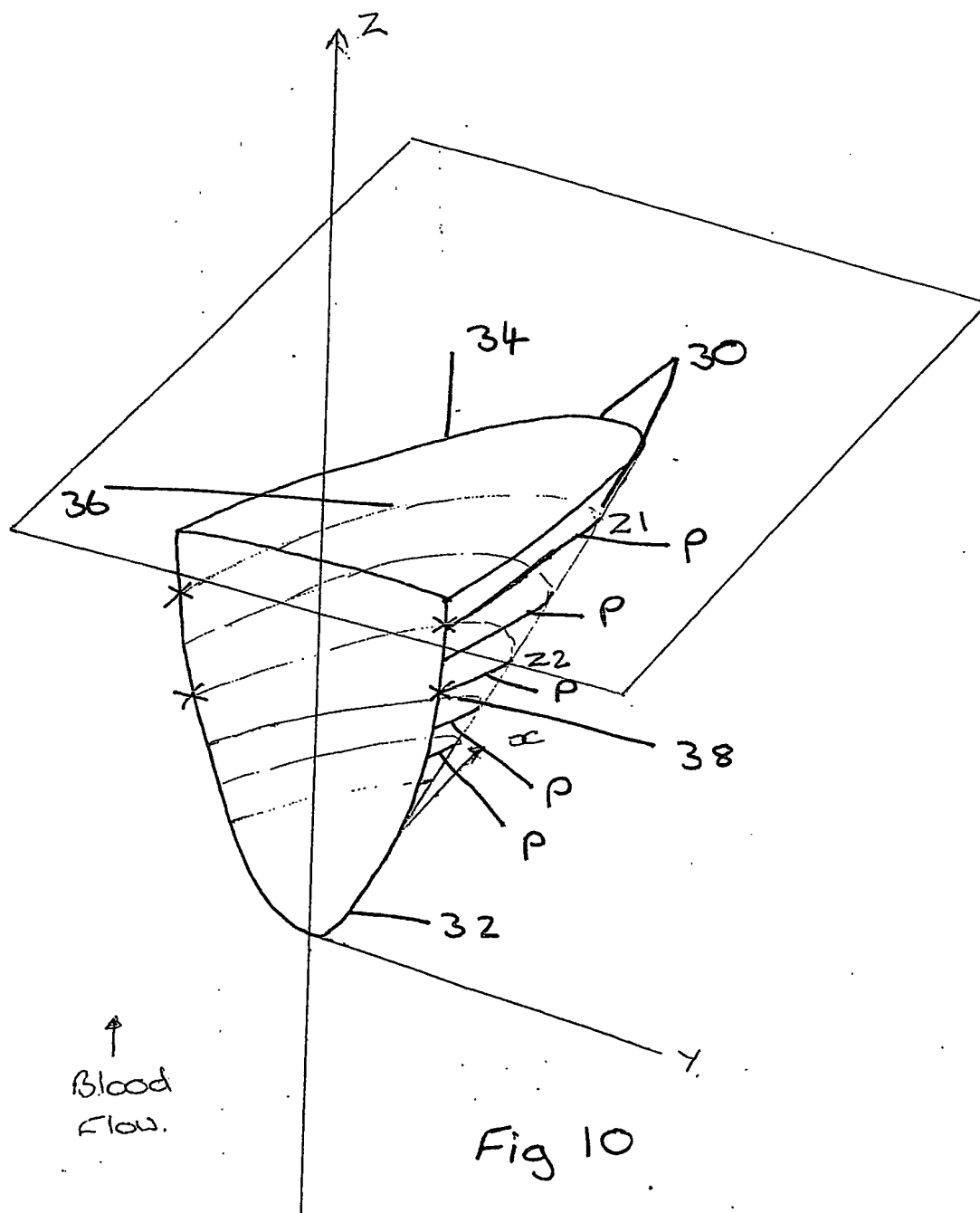
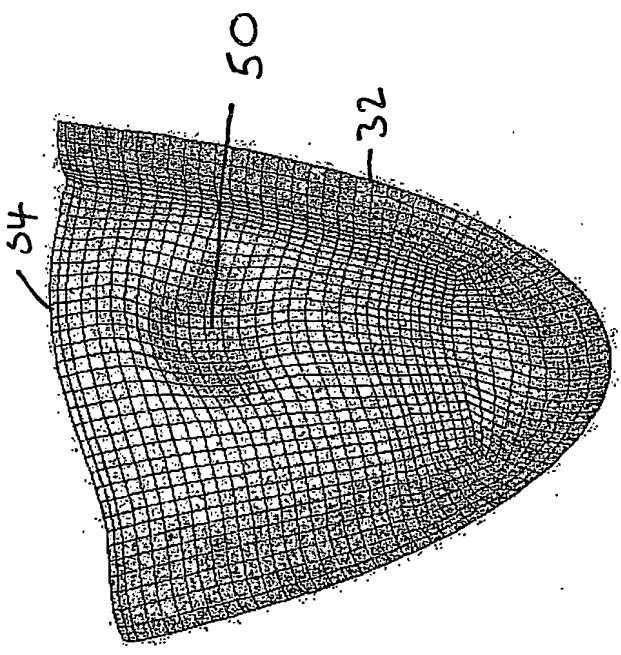
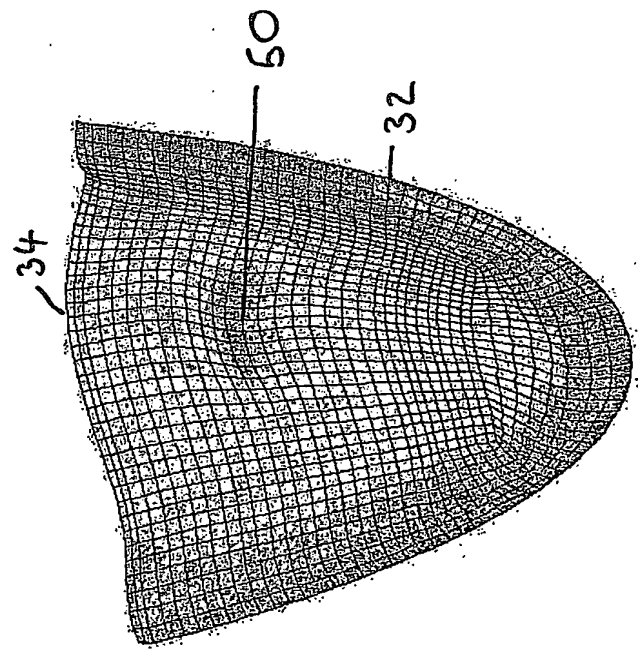


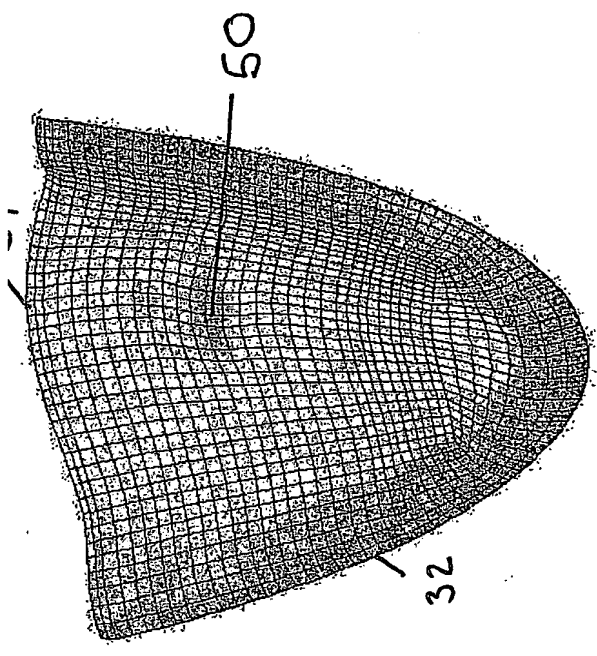
Fig 10



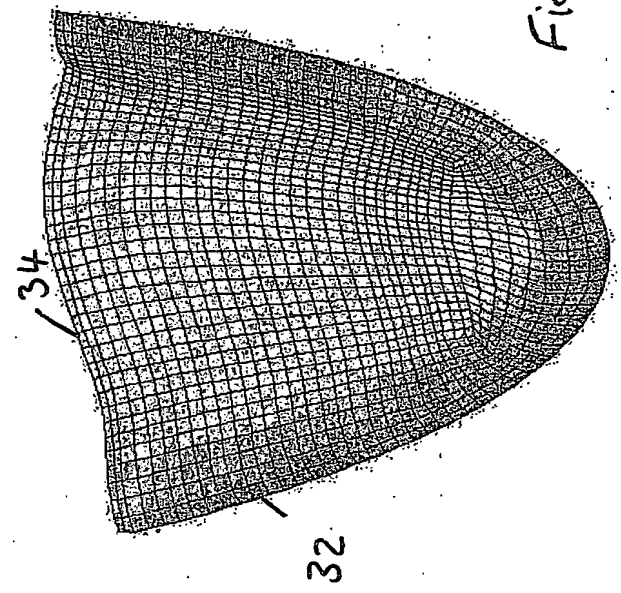
(a)



(b)



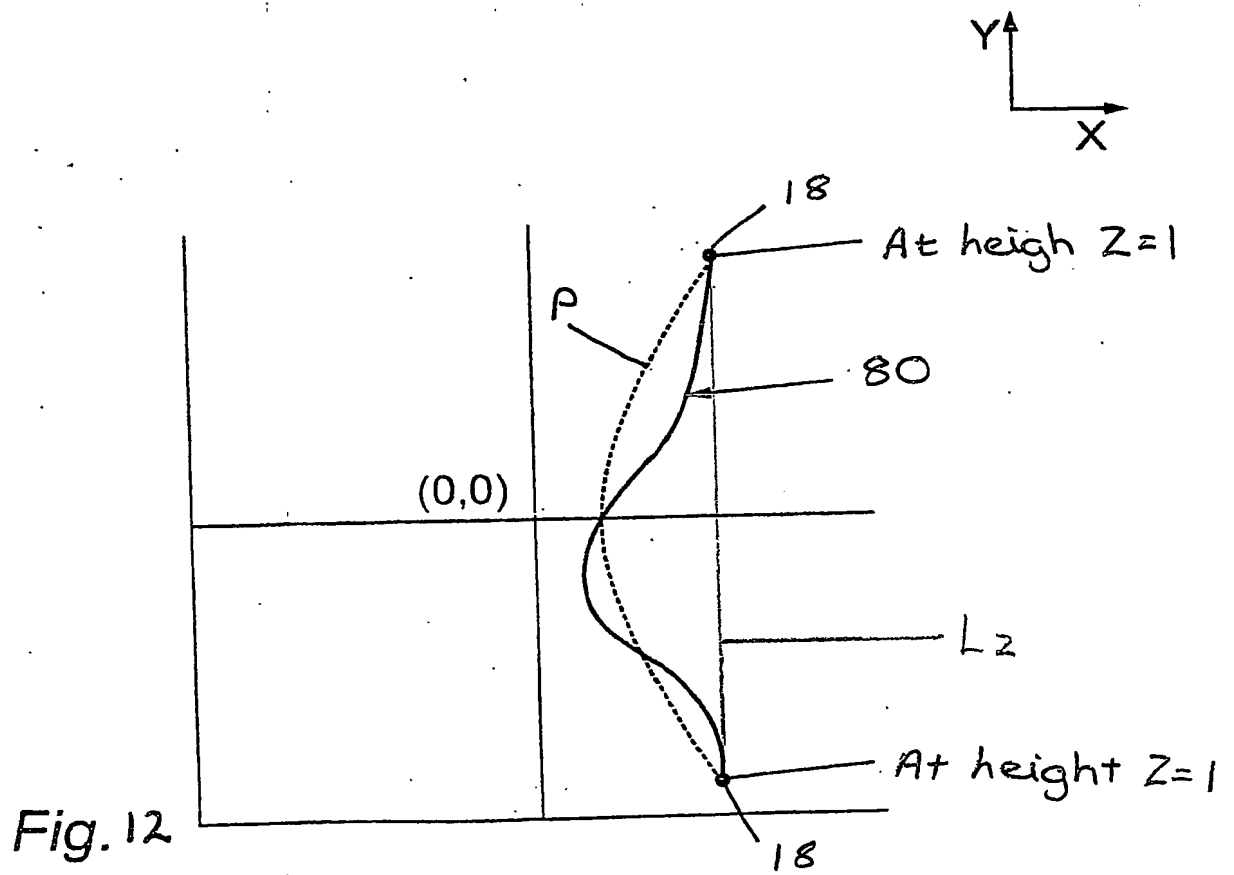
(c)



(d)

Fig 11

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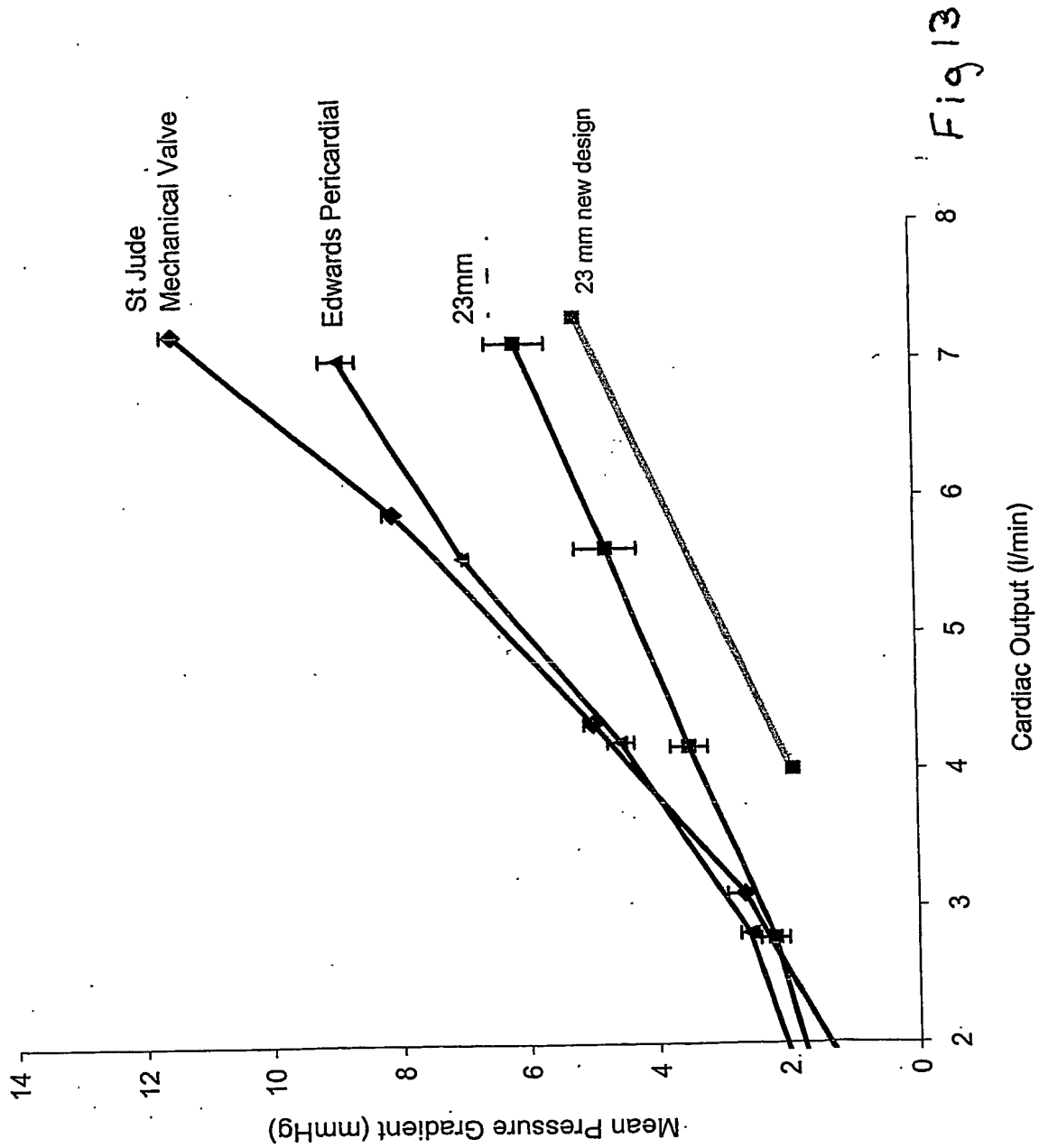


Fig 13

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